

**UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
MARSHALL DIVISION**

APICORE US LLC and MYLAN  
INSTITUTIONAL LLC,


Plaintiffs,

v.

BELOTECA, INC.,

Defendant.

Civil Action No. 2:19-cv-00077-JRG



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**APICORE US LLC'S AND MYLAN INSTITUTIONAL LLC'S  
OPPOSITION TO BELOTECA'S MOTION TO DISMISS**

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## I. INTRODUCTION

Defendant Beloteca, Inc.’s (“Beloteca”) attempt to remove the case from this Court involves an overly broad application of the first-to-file rule. As Beloteca would have it, any later-filed case that is substantially similar to one filed earlier in a different district should automatically be transferred to the latter to determine venue. Beloteca omits any consideration of the exceptions to the first-to-file rule “that would make it unjust or inefficient to continue the first-filed action,” which—as the very authority Beloteca relies upon indicates—may include “judicial and litigant economy” and the “absence of jurisdiction over all necessary or desirable parties.” *Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 937, 938 (Fed. Cir. 1993). Because this Court has prior experience with the patents-in-suit, and because the Court in the Northern District of Illinois (the “Illinois Court”) lacks subject matter jurisdiction over Beloteca’s preemptive suit and lacks personal jurisdiction and venue over Apicore US, LLC (“Apicore”), a necessary and indispensable party, the exceptions compel denying Beloteca’s request on first-to-file grounds.

Beloteca’s alternate grounds for dismissal (lack of venue and/or personal jurisdiction) also do not compel dismissal or transfer. Beloteca has expressed its intent to market (directly or indirectly) an infringing isosulfan blue (“ISB”) injection 1% product (the “ISB Product”) throughout the United States, which necessarily includes this District as Texas, of course, is one of the largest markets for ISB. These manifestations are sufficient to confer personal jurisdiction in this Court. Beloteca’s assertions otherwise are contrary to the Federal Circuit’s decision in *Acorda Therapeutics, Inc. v. Mylan Pharmaceuticals, Inc.*, 817 F.3d 755 (Fed. Cir.

2016). Because personal jurisdiction is appropriate in this Court, so too is venue.<sup>1</sup> Accordingly, this Court should deny Beloteca's Motion to Dismiss for Lack of Personal Jurisdiction, Improper Venue, and Prior Pending Action ("Motion to Dismiss"). (Dkt. No. 21.)

## **II. STATEMENT OF THE ISSUES TO BE DECIDED**

1. Whether the Illinois Court's lack of subject matter jurisdiction over Beloteca's preemptive suit and lack of personal jurisdiction over Apicore, a necessary and indispensable party, and this Court's prior experience with the patents-in-suit nullify any applicability of the first-to-file rule.

2. Whether this Court may exercise personal jurisdiction over Beloteca, and thus whether venue is proper here under 28 U.S.C. § 1391, where Beloteca holds an FDA-approved ANDA to market its ISB Product nationwide, has publicly stated its intent to market its ISB Product nationwide, [REDACTED], and has sought a judicial declaration that the manufacture, use, sale, offering for sale, or importation of its ISB Product will not infringe any valid claim of the patents-in-suit.

## **III. FACTUAL BACKGROUND**

### **A. Beloteca**

Beloteca is a startup pharmaceutical company with 3 to 25 employees in San Diego, California focused on "developing [] products and taking them all the way to FDA approval." Declaration of Fred Defesche in Support of Motion to Dismiss ("Defesche Decl."), Dkt. 21-1, ¶¶ 2, 4; Motion at 4; D-13 at 4. Beloteca's registered agent and CEO, Mr. Defesche, owns

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<sup>1</sup> Because Plaintiffs Apicore and Mylan Institutional LLC ("Mylan Institutional") (collectively, "Plaintiffs") seek a declaratory judgment, 28 U.S.C. § 1391 governs venue.

property in Travis County, Texas [REDACTED] (Exs. 1 & 2.)

On July 26, 2017, Beloteca submitted ANDA No. 210714 to the FDA for approval to market an ISB product. ([REDACTED]) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] On January 16, 2019, the FDA approved ANDA No. 210714.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

#### **B. Apicore**

Apicore is a Delaware LLC with a single place of business in the United States: a manufacturing facility in Somerset, New Jersey. (Ex. 7, Declaration of Ravishanker Kovi (“Kovi Decl.”) at ¶¶ 4, 14.) Apicore has no offices or facilities in Illinois, nor does it own or lease any other real property there. (*Id.* at ¶ 5.) Similarly, it has no officers or employees in



Illinois, no agent for receipt of service in Illinois, no telephone listing or mailing address in Illinois, no bank accounts in Illinois, and it does not pay taxes to the state of Illinois. (*Id.* at ¶¶ 5-7.)

#### **IV. PROCEDURAL BACKGROUND**

##### **A. District Court Proceedings**

##### **1. Beloteca Sued Plaintiffs Anticipatorily and in the Wrong Forum**

On January 17, 2019, Beloteca filed a declaratory judgment complaint against Plaintiffs in the Northern District of Illinois, just one day after Beloteca received FDA approval of its ANDA. (Ex. 8, *Beloteca, Inc. v. Apicore US LLC.*, No. 1:19-cv-00360 (N.D. Ill.), ECF No. 1.) Beloteca alleged that “Based on the approval of its ANDA No. 210714, Plaintiff Beloteca intends to manufacture, market, distribute and/or sell in the United States and this District the isosulfan blue product that is the subject of ANDA No. 210714.” (*Id.* at ¶ 28.) Beloteca further alleged that it was “entitled to a judicial declaration that the manufacture, use, sale, offering for sale, or importation of the isosulfan blue for injection product that is the subject of ANDA No. 210714 will not infringe, directly or indirectly, any valid claim of the [patents-in-suit].” (*Id.* at ¶¶ 36, 40, 45.)

Beginning the day after Beloteca filed its complaint, Plaintiffs sought informal discovery from Beloteca to evaluate Beloteca’s ISB Product and its manufacturing process, and requested Beloteca forego any launch of its product pending resolution on the merits. (Ex. 9, Jan. 18, 2019 Ltr from Stafford to Mizerk). Beloteca would not agree, however, unless Plaintiffs waived any objections to personal jurisdiction and venue in the Illinois Court. (Ex. 10, Jan. 24, 2019 Ltr from to Stafford). On February 4, Plaintiffs made it absolutely clear that they believed the parties’ dispute should be litigated in Texas. (Ex. 11, Feb. 4, 2019 Ltr from Stafford to Mizerk) (“To put it bluntly, this case should be tried in the Eastern District of Texas. That court

is familiar with the patents-in-suit and it is the most appropriate forum.”). Over the next five weeks, Plaintiffs continued to negotiate with Beloteca, seeking information about Beloteca’s product and an assurance that Beloteca would not launch until the case was decided on the merits.<sup>2</sup> Ultimately, the parties could not reach agreement.

Accordingly, on March 5, 2019, Plaintiffs filed a motion to dismiss and/or transfer the case to this Court on March 5, 2019—eight days before its deadline to respond to Beloteca’s complaint. (*See* Ex. 13, *Beloteca, Inc. v. Apicore US LLC*, No. 1:19-cv-00360 (N.D. Ill.), ECF No. 18.) Plaintiffs’ first ground for dismissal or transfer was that the Illinois Court lacked subject matter jurisdiction over the action because Plaintiffs had never threatened Beloteca with a lawsuit; indeed, Plaintiffs had no prior knowledge of Beloteca’s existence. (*See* Ex. 14, *Beloteca, Inc. v. Apicore US LLC*, No. 1:19-cv-00360 (N.D. Ill.), ECF No. 24.) (“Illinois MTD Brief.”) (citing Kovi Decl. at ¶¶ 21-22.)<sup>3</sup> Plaintiffs’ second ground for dismissal or transfer was that the Illinois Court lacked personal jurisdiction over Apicore, a necessary and indispensable party. (*See* Illinois MTD Brief at pp. 11-29.) In the alternative, Plaintiffs moved to transfer under 28 U.S.C. 1404(a). (*Id.* at pp. 30-35.) Plaintiffs’ motion is pending.

## 2. Plaintiffs Sought Injunctive Relief in the Appropriate Forum

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<sup>2</sup> Upon review of Beloteca’s production, [REDACTED]

<sup>3</sup> As noted above, the existence of Beloteca’s ANDA was not publicly known until it received FDA approval. Plaintiffs first learned of Beloteca and its ANDA when they were sued the next day.

Around the same time, on March 4, 2019, Plaintiffs filed a declaratory judgment complaint against Beloteca in this Court. (Dkt. No. 1.) Plaintiffs contemporaneously filed a Motion for Temporary Restraining Order and a Motion for Expedited Discovery. (Dkt. Nos. 5, 6.) Because Beloteca refused to provide assurances that it would forego launching until the merits of Plaintiffs' request for a preliminary injunction were resolved in the Illinois Court absent unreasonable conditions, these declaratory judgment proceedings were Plaintiffs' only recourse, absent waiving Apicore's valid objections to personal jurisdiction and venue in Illinois.

Beloteca filed its Motion to Dismiss on March 12, 2019. (Dkt. No. 21.) Contrary to its suggestion therein, (*see id.* at 9), Plaintiffs were not required to seek injunctive relief from the Illinois Court. Indeed, Plaintiffs may have waived their personal jurisdiction and venue objections if they had. And, given that Court's lack of subject matter jurisdiction, any attempt to do so likely would have been in vain.

## **V. APPLICABLE LEGAL STANDARDS**

### **A. First-to-File Rule**

Virtually every court in the Fifth Circuit has applied Fifth Circuit law when deciding "whether the second-filed court should transfer a case to the first-filed court under the first-to-file rule." *SIPCO, LLC v. Emerson Electric Co.*, NO. 6:15-cv-907, 2016 WL 7743496 at \*3 (E.D. Tex. July 1, 2016).<sup>4,5</sup> Under Fifth Circuit law, when a motion to dismiss or transfer is

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<sup>4</sup>Federal Circuit law applies a similar standard as Fifth Circuit law. The only notable difference appears to be the amount of overlap necessary to trigger the rule. The Federal Circuit describes a "sufficient overlap" while the Fifth Circuit describes a "substantial overlap." *Compare Futurewei Technologies, Inc. v. Acacia Research Corp.*, 737 F.3d 704, 708 (Fed. Cir. 2013), with *Mann Mfg., Inc. v. Hortex Inc.*, 439 F.2d 403, 407 (5th Cir. 1971).

<sup>5</sup> Of note, at the March 12, 2019 hearing, the Illinois Court commented that the "Seventh Circuit doesn't follow the first-to-file rule." (Ex. 16, March 12, 2019, Hr'g Tr. at 7:14-8:2).

filed with the second-filed court, “the second-filed court must make a determination as to likelihood of substantial overlap and, if this threshold is met, the second-filed court must then transfer the action to the first-filed court to determine the ultimate disposition of the case.” *Id.* However, exceptions to the first-to-file rule “are not rare and are made when justice or expediency requires.” *Id.* at \*4. Specifically, a party may avoid “application of the first-to-file rule” by “show[ing] the existence of compelling circumstances,” such as “considerations of judicial and litigant economy, and the just and effective disposition of disputes.” *Mobility Elecs., Inc. v. Am. Power Conversion Corp.*, No. 5:07-cv-00083, 2007 WL 9724768 at \*3 (E.D. Tex. Oct. 10, 2007). If the plaintiff in the second-filed action meets this burden, the court may ignore the first-to-file rule. *See id.* at \*2.

#### **B. Personal Jurisdiction and Venue**

There is no binding precedent on whether Federal Circuit law or Fifth Circuit law governs the venue and personal jurisdiction inquiries in a declaratory judgment action brought by a patentee against a potential infringer. In the reverse scenario where the patentee is the declaratory judgment defendant, Federal Circuit law controls. *See Akro Corp. v. Luker*, 45 F.3d 1541, 1543 (Fed. Cir. 1995). Further, in a civil action for patent infringement, Federal Circuit law controls. *In re ZTE (USA) Inc.*, 890 F.3d 1008, 1012-13 (Fed. Cir. 2018).

A district court may assert personal jurisdiction over a non-resident defendant if the defendant is “subject to the jurisdiction of a court of general jurisdiction in the state where the district court is located.” *Johnston v. Multidata Sys. Int’l Corp.*, 523 F.3d 602, 609 (5<sup>th</sup> Cir. 2008). “Because the Texas long-arm statute extends to the limits of federal due process, the two-step inquiry collapses into one federal due process analysis.” *Id.* For due process to be satisfied, the defendant must have “certain minimum contacts with [the forum] such that the

maintenance of the suit does not offend traditional notions of fair play and substantial justice.”

*Int’l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945) (internal quotations omitted).

Upon a showing of purposeful minimum contacts, the defendant bears the burden to prove unreasonableness. *Elecs. for Imaging, Inc. v. Coyle*, 340 F.3d 1344, 1350 (Fed. Cir. 2003). In rare circumstances, a defendant may defeat the exercise of personal jurisdiction by “present[ing] a compelling case that the presence of some other considerations would render jurisdiction unreasonable.” *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 477 (1985).

## **VI. ARGUMENT**

When Beloteca was first to the Illinois courthouse, it was the only party who knew there was a race. Now, by asking this Court to yield to the first-filed court, Beloteca seeks an award for this unfair advantage. Compelling circumstances weigh against doing so. Controlling Federal Circuit law establishes that the Illinois Court lacks subject matter jurisdiction over Beloteca’s action. In addition, other factors, such as the Illinois court’s lack of personal jurisdiction over the patentee Apicore, a necessary and indispensable party, and judicial and litigant economy, are compelling reasons for this Court not to follow the first-to-file rule. In contrast, personal jurisdiction and venue are proper here.

### **A. The First-to-File Rule Does Not Require This Court to Dismiss, Stay, or Transfer This Case**

Exceptions to the first-to-file rule are fatal to Beloteca’s request for this Court to yield to the Illinois Court. *See* Motion at 10-13. Indeed, exceptions “are not rare and are made when justice or expediency requires.” *SIPCO*, 2016 WL 7743496 at \*3; *see also Coyle*, 394 F.3d at 1347 (“‘Exceptions ... are not rare,’ but we have explained that ‘[t]here must . . . be sound reason that would make it unjust or inefficient to continue the first-filed action.’”) (quoting *Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 937-38 (Fed. Cir. 1993)).

Here, Beloteca sued Plaintiffs in the Illinois Court prior to any communications ever being made between them and Plaintiffs. Because Beloteca's head start provided it with an unfair advantage, and also prevents the Illinois Court from having subject matter jurisdiction over Beloteca's action, sound reason would make it unjust for this Court to yield to the first-filed action. (*See* Ex. 15, Illinois Motion to Dismiss at p. 5; *see also Coyle*, 394 F.3d at 1347; *Kerotest Mfg. Co. v. C-O-Two Fire Equipment Co.*, 342 US 180, 185 (1952) (stating that the accused infringer "is given an equal start in the race to the courthouse, not a headstart"); *Innovative Therapies, Inc. v. Kinetic Concepts, Inc.*, 599 F.3d 1377 (Fed. Cir. 2010) (finding lack of subject matter jurisdiction despite more significant pre-suit communications than those here).

There are other compelling reasons why this Court should "ignore the first-to-file rule." *Mobility Elecs., Inc. v. Am. Power Conversion Corp.*, No. 5:07-cv-00083, 2007 WL 9724768 at \*3 (E.D. Tex. Oct. 10, 2007). The Illinois Court's lack of personal jurisdiction over the patentee Apicore, a necessary and indispensable party, and judicial and litigant economy favor proceeding in this Court.

Furthermore, because Beloteca did not address any of the section 1404(a) factors concerning whether transfer is appropriate in the event this Court does not apply the first-to-file rule, this Court should keep this case. Notwithstanding Beloteca's oversight, the § 1404(a) factors do not support transfer to the Illinois Court.

**1. The Northern District of Illinois Lacks Subject Matter Jurisdiction under *Innovative Therapies, Inc. v. Kinetic Concepts, Inc.***

The Illinois Court lacks subject matter jurisdiction under the Federal Circuit’s decision in *Innovative Therapies, Inc. v. Kinetic Concepts, Inc.*, 599 F.3d 1377 (Fed. Cir. 2010).<sup>6</sup> In *Innovative Therapies*, the declaratory judgment plaintiff (potential infringer) asserted three premises which purportedly supported subject matter jurisdiction: 1) the patentee-defendant’s knowledge of plaintiff’s communications with the FDA stating that the plaintiff’s products had the “same technological features”; 2) the patentee’s employee’s statements that it would sue if the plaintiff launched its product; and 3) the patentee’s prior patent enforcement history against third parties. *Innovative Therapies*, 599 F.3d at 1379-82. The Federal Circuit found that none of these facts alone or in combination established subject matter jurisdiction. *Id.*

The pre-suit facts in the Illinois action are even less conducive to subject matter jurisdiction than those in *Innovative Therapies*. Prior to the filing of Beloteca’s complaint, Plaintiffs never communicated with Beloteca nor threatened suit. *See supra* IV.A.1. In fact, until they received the complaint, Plaintiffs were unaware of Beloteca’s existence, its ANDA submission or approval, and its anticipated ISB product. *See id.* The Illinois Court’s lack of subject matter jurisdiction alone supports the inapplicability of the first-filed rule.

**2. Other Factors Do Not Support Application of the First-to-File Rule**

Other factors also support not following the first-to-file rule. First, even if the Illinois Court were to have subject matter jurisdiction, which it does not, this Court should view Beloteca’s action as a preemptive suit, which weighs against applicability of the first-to-file rule. *See Mobility Elecs.*, 2007 WL 9724768 at \*3; *see also Serco Servs. Co., L.P. v. Kelley*

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<sup>6</sup> Plaintiffs’ argument on why the Illinois Court lacks subject matter jurisdiction is set forth in its Motion to Dismiss the Illinois Action. *See* Illinois MTD Brief, pp. 8-11.

*Co.*, 51 F.3d 1037, 1040 (Fed. Cir. 1995) (holding no abuse of discretion to consider whether the accused infringer intended to preempt the patentee’s infringement suit when deciding if the first-to-file rule applied).

Second, the Illinois Court lacks personal jurisdiction over Apicore—the patentee—who is a necessary and indispensable party.<sup>7</sup> *See Genentech*, 998 F.2d at 938 (One reason that would make it unjust or inefficient to continue the first-filed action “may be the . . . ***absence of jurisdiction over all necessary or desirable parties***”) (emphasis added). The Illinois Court does not have general personal jurisdiction over Apicore because it is not incorporated in Illinois, does not have its principal place of business there, and it does not have substantial operations in Illinois such that it could be called “at home” there. *Daimler AG v. Bauman*, 571 U.S. 117, 138-39, n. 19 (2014); *see supra* IV.A.2. The Illinois Court also lacks specific personal jurisdiction over Apicore because Apicore has never sought to enforce the patents-in-suit in Illinois. *See, e.g., Torrent Pharms. Ltd v. Daiichi Sankyo, Inc.*, 196 F.Supp.3d 871, 881-82 (N.D. Ill. 2016).

A third factor that courts consider when deciding to apply the first-to-file rule is judicial economy. This Court has prior experience with the patents-in-suit having presided over Plaintiffs’ action against AuroMedics through resolution of Plaintiffs’ preliminary injunction motion.

Accordingly, this Court should not dismiss, stay, or transfer this case.<sup>8</sup>

### **3. Beloteca Fails to Establish that Any § 1404(a) Convenience Factors Support Transfer**

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<sup>7</sup> Plaintiffs’ argument on why the Illinois Court lacks personal jurisdiction over Beloteca is set forth in its Motion to Dismiss the Illinois Action. *See* Illinois MTD Brief, , pp. 11-29.

<sup>8</sup> If this Court is inclined to grant Beloteca’s motion, Plaintiffs agree that the Court should transfer this action in the interests of justice. All the preliminary injunction briefing has been before this Court and the parties have already entered into a cross-use agreement for any discovery produced in this action or the Illinois action.



This Court should also keep this case because Beloteca does not even seek transfer under 28 U.S.C. § 1404(a) in the alternative, *see* Motion at 13-16. For example, in *Mobility Elecs.*, the movant in the second-filed suit alternatively sought a motion to transfer under 28 U.S.C. § 1404(a). 2007 WL 9724768 at \*5. Thus, after the district court found that compelling factors demonstrated inapplicability of the first-to-file rule, the court still analyzed the private and public interest factors under 28 U.S.C. § 1404(a). Here, Beloteca only mentions transfer as an alternative to dismissing the action in the “interests of justice.” *See* Motion at 15 (“The ‘interests of justice’ warrant transfer, in lieu of dismissal, when ‘time-consuming and justice defeating technicalities would penalize the plaintiff or prevent the case from being heard on the merits in the proper venue.’”). Beloteca, however, makes no showing that balancing the convenience factors favors transfer, and, in fact several interests of justice factors weigh against it.

#### **4. Docket Congestion and Likely Speed to Trial in the Transferor and Potential Transferee Forums**

The comparative docket congestion and likely speed to trial strongly favors this Court. According to PricewaterhouseCoopers’ 2018 Patent Litigation Study, the median time-to-trial for patent litigation cases was 4.0 years in the Illinois Court, but only 2.2 years in this Court. *See* (Ex. 19, “PricewaterhouseCoopers’ 2018 Patent Litigation Study” at 14.) Similarly, the Federal Court Management Statistics, September 2018 Report, shows a median time to trial of 37.8 months for civil cases in the Illinois Court, in contrast to 19.1 months for civil cases in this Court. (*See* Ex. 20, “Federal Court Management Statistics, September 2018 Report” at 1-2.) The same Report indicates there are 762 pending cases per judge in the Illinois Court and 621 pending cases per judge in this Court. (*Id.*) These statistics emphasize that this Court will likely be the faster forum, which weighs strongly against transfer. *See RAH Color Techs. LLC v.*

*Quad/Graphics, Inc.*, 2018 WL 439210, at \*5 (N.D. Ill. Jan. 16, 2018) (finding that court statistics weighed in favor of transfer where the median time to trial was three months less in the transferee district—33.7 months vs. 36.8 months—and the number of cases per judge was lower in the transferee district).

**5) Each Court’s Relative Familiarity with the Relevant Law**

Although this Court and the Illinois Court are both familiar with patent law, this Court is more familiar with the patents-in-suit based on its prior experience with the AuroMedics litigation. Indeed, this Court has already overseen litigation of the patents-in-suit through issuance of a preliminary injunction.

**6) This Court Has Personal Jurisdiction Over All Parties As It Relates to ISB.**

The absence of jurisdiction over all necessary or desirable parties and the possibility of consolidation of related litigation weigh against transfer to Illinois. *See Serco Servs.*, 51 F.3d at 1040 (Fed. Cir. 1995) (observing lack of personal jurisdiction over all necessary or desirable parties is a proper consideration under *Genentech*, 998 F.2d at 938). As explained in Section VI.A.2 *supra*, the Illinois Court lacks personal jurisdiction over Apicore, a necessary and indispensable party.

In contrast, this Court has personal jurisdiction over all parties. This Court has personal jurisdiction over Beloteca, as explained *infra* at VI.B. In addition, because Plaintiffs previously sued AuroMedics in this Court on the same patents, this Court would have had personal jurisdiction over Plaintiffs if Beloteca had brought its declaratory judgment action here. *See Xilinx, Inc. v. Papst Licensing GmbH & Co. KG*, 848 F.3d 1346, 1357–58 (Fed. Cir. 2017) (holding court had personal jurisdiction over defendant patent owner, in part because defendant had previously sued to enforce the patent multiple times in the district). Accordingly, if the

Illinois Court were to transfer its action here, it could be consolidated with the existing lawsuit, which would conserve the courts' and the parties' resources. Thus, resolution of the dispute in this Court would further the goal of judicial economy.

Taking each of the above interest of justice factors into account, the totality of the factors weighs against transfer.

**B. This Court Has Personal Jurisdiction over Beloteca, and Thus Venue Is Proper under the Correct Governing Venue Statute, 28 U.S.C. § 1391**

The Federal Circuit's decision in *Acorda* establishes that Beloteca's contacts with this District comports with due process, thus the Court has personal jurisdiction over Beloteca. Furthermore, under the correct governing statute—28 U.S.C. § 1391—venue is proper here because this Court has personal jurisdiction over Beloteca. Under 28 U.S.C. § 1391(b), as relevant here, “venue is proper in a district: (1) ‘in which any defendant resides. . . .’” *See Luci Bags LLC v. Yunique, LLC*, No. 4:16-cv-377, 2017 WL 77943, at \*3 (E.D. Tex. Jan. 9, 2017). “For venue purposes, a defendant entity is deemed to reside in any judicial district where it would be subject to the court's personal jurisdiction with respect to the civil action in question.” *Id.* (citing 28 U.S.C. § 1391(c)(2)).

**1. Beloteca Has Minimum Contacts with This District under *Acorda***

Based on *Acorda*, this District meets the minimum contacts requirement. In *Acorda*, the Federal Circuit held that the defendants' ANDA filings and distribution channels, established its plan to market its proposed drugs in the State, satisfying the minimum contacts requirement. *Acorda*, 817 F.3d at 762. In addition, *Acorda* specifically rejected the defendant's argument that it had to have committed acts of infringement in the State, as opposed to “planned future conduct in the State” to meet the minimum-contacts standard. *Id.* (“Mylan does not show that a State is forbidden to exercise its judicial power to prevent a defendant's planned future

conduct in the State, but must wait until the conduct occurs.”) The court further explained, that “as long as the connection to the planned acts is close enough, the subject of such actions readily fits the terms of the minimum-contacts standard—conduct purposefully directed at the State that gives rise and is related to the suit.” *Id.*

Following *Acorda*, this Court has previously found sufficient minimum contacts where a defendant’s “ANDA is to market [its drug] nationwide, including in Texas and within this district as [Plaintiff’s] Complaint plausibly allege[d].” *Warner-Chilcott v. Mylan Pharms., Inc.*, 2017 WL 603309, at \*2 (E.D. Tex. Jan. 19, 2017); *see also Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 2:15-CV-1455-WCB, 2016 WL 1572193, at \*3 (E.D. Tex. Apr. 19, 2016) (Bryson, J., sitting by designation) (“The Federal Circuit explained that by filing an ANDA a drug company ‘confirm[s] its plan to commit real-world acts that would make it liable for infringement if it commits them without the patentees’ permission.”) (citation omitted). Indeed, Beloteca agrees that “the submission of an ANDA with a ¶ iv certification establishes the *second* part of the personal jurisdiction in a Hatch-Waxman case. . . .,” Motion at 19 (citing *Acorda*, 817 F.3d at 761), but attempts to distinguish itself by asserting that this case is not a Hatch-Waxman case. *See id.*

However, whether a case is a Hatch-Waxman case does not affect the applicability of *Acorda*. What matters is that the defendant filed an ANDA and challenged the validity and/or the infringement of the patents, which Beloteca has done both. Thus, as stated in the portion of *Acorda* that Beloteca cites, “it has, by its filing, reliably confirmed a plan to engage in real-world marketing.” *Id.* As Beloteca states, “[F]iling an ANDA with the FDA relates to other marketing activity directed towards the particular forum [] because an ANDA is a ‘costly, significant step of applying to the FDA for approval to engage in further activities—including

the marketing of its generic drugs—that will be purposefully directed at the [forum] (*and, it is undisputed, elsewhere*).’” *Id.* (quoting *Acorda*, 817 F.3d at 759 (emphasis added)).

That this case is not a Hatch-Waxman case also does not alter Beloteca’s admission that “[s]ubmitting an ANDA with a ¶ iv certification is the claim that ‘arises out of or relates to the defendant’s activities with the forum state’ because it relates to marketing preparations.” Motion at 19 (citing *Grober v. Mako Prods., Inc.*, 686 F.3d 1335, 1346 (Fed. Cir. 2012)). As discussed above, *Acorda* viewed the filing of the ANDA and the substantial costs associated with it, and not the paragraph IV certification, as the critical fact in determining personal jurisdiction.

Because, at its base, a paragraph IV certification is a challenge to either the validity and/or the infringement of the patent covering the drug in question, Beloteca’s actions are not dissimilar. Instead of filing an ANDA containing a paragraph IV certification that challenged the patents, Beloteca filed a declaratory judgment action that did. *See supra* IV.A.1. As such, Beloteca’s actions—filing an ANDA and challenging the validity and/or infringement of the patents—mirror that of the ANDA filers’ paragraph IV certification in *Acorda* in relevant respects.

Thus, Beloteca’s Hatch-Waxman distinction is of no consequence, and *Acorda* supports finding that Beloteca’s ANDA provides minimum contacts to this District.<sup>9</sup>

Furthermore, the facts here more strongly support the exercise of personal jurisdiction. Unlike in either *Warner-Chilcott*, *Allegran*, or *Acorda*, Beloteca has already received FDA

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<sup>9</sup> Beloteca contends that it was not Mylan’s filing of an ANDA in *Acorda* which provided minimum contacts sufficient to show personal jurisdiction, but instated its “directing of sales into Delaware.” *See* Motion at 19. As the preceding discussion shows, this interpretation of *Acorda* is incorrect.

approval for its ANDA, which makes any future marketing and sales much less speculative.

Another difference that makes the exercise of personal jurisdiction more appropriate here is that Beloteca has stated publicly that it “intends to manufacture, market, distribute and/or sell in the United States . . . the isosulfan blue drug product that is the subject of ANDA No. 210714” [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *See supra* at III.A.

Beloteca’s argument that *Zeneca* controls the determination of personal jurisdiction and that “merely filing an ANDA, standing alone, is insufficient to establish personal jurisdiction” is disingenuous. Motion at 17. *Zeneca* is clearly inapplicable to the facts or allegations here. The question presented in *Zeneca* was “whether, in light of the government contacts exception, personal jurisdiction over Mylan in the District Court for the District of Maryland is supported by Mylan’s contacts with the FDA in Rockville, Maryland pursuant to 35 U.S.C. § 271(e)(2).” *Zeneca Ltd. v. Mylan Pharm., Inc.*, 173 F.3d 829, 830-31 (Fed. Cir. 1999). Here, Plaintiffs do not rely on “government contacts” to establish personal jurisdiction over Beloteca. Indeed, if they were, they would have brought this case in Maryland where the FDA is located.

Moreover, as *Acorda* acknowledged, *Zeneca* “was decided without any majority opinion, and neither of the two single-judge opinions . . . addresse[d] whether the location of the ANDA filer’s future sales could support specific personal jurisdiction over the filer in the § 271(e)(2) suit, so *Zeneca* is not precedent on that issue.” *Acorda*, 817 F.3d at 763.

Equally unavailing is Beloteca’s argument that Plaintiffs have not alleged facts similar to those in traditional Hatch-Waxman cases. *See* Motion at 4. To start, it is rather ironic that

Beloteca critiques Plaintiffs’ allegations for not being like those in Hatch-Waxman cases in light of Beloteca’s oft-repeated refrain that this is not a Hatch-Waxman case. Nonetheless, Plaintiffs’ allegations in their complaint are sufficient to show minimum contacts under *Acorda*. (See TX Complaint at ¶¶ 15-20, 32.) Those paragraphs, in brief, allege that this Court has personal jurisdiction over Beloteca because its filing of an ANDA is a significant and costly step taken for the purpose of engaging in injury-causing and wrongful marketing conduct in Texas and this District, especially when coupled with Beloteca’s public statement of its intent to engage in the marketing of its ISB Product throughout the United States without any limitations. (*Id.*) Accordingly, as paragraph 19 of the complaint states, “Beloteca’s ANDA conduct is therefore suit-related and has a substantial connection with Texas and this District because Beloteca’s ANDA filing is tightly tied, in purpose and planned effect, to the deliberate making of sales in Texas and this District and the suit relates to whether that in-State activity will infringe Apicore’s Patents-in-Suit.” (*Id.* at ¶ 19.)

Beloteca attempts to avoid the truth that Plaintiffs have alleged facts sufficient for minimum contacts by asserting that Plaintiffs’ allegation are conclusory. See Motion at 21. For example, Beloteca asserts that the allegation made in paragraphs 3 and 18 of the complaint are conclusory and legally insufficient. See *id.* A quick glance at the allegations proves Beloteca’s assertion untrue. Indeed, paragraph 3, which is a direct quote from Beloteca’s declaratory judgment complaint, states:

“Beloteca has stated in a public filing that ‘Based on the approval of its ANDA No. 210714, Plaintiff Beloteca intends to manufacture, market, distribute and/or sell in the United States . . . the isosulfan blue product that is the subject of ANDA No. 210714.’”

TX Complaint at 3.

The allegation merely states what Beloteca itself put forth in its declaratory judgment complaint. Plaintiffs simply repeated facts Beloteca put in its complaint. In addition, that Plaintiffs omitted “and this District” makes Beloteca’s allegation no less factual. Inserting “and this District” does not change the fact that Beloteca has publicly stated its intent to market its ISB product nationwide without any limitations as to where. As such, Plaintiffs’ allegations in paragraphs 3 and 18, taken as true, plausibly allege that Beloteca will manufacture, market, distribute, and sell its ISB Product in the United States, including this District. The Court in *Allergan* found similarly. In *Allergan*, defendants, like Beloteca here, challenged Plaintiffs’ allegations that they would sell in Texas as “nothing more than baseless allegations.” *Allergan*, 2016 WL 1572193, at \*3. Judge Bryson rejected such a challenge, noting that the defendants “have not represented that they will not sell nationally, including in Texas, if they receive FDA approval. Nor have they offered any reason to believe that it is at all likely that they would sell their product in some States, but not in Texas.” *Id.*

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

██████████ Texas is one of the largest markets for ISB, ██████████

<sup>10</sup> Additional information may have been elicited from a deposition of Fred Defesche, Beloteca's CEO and declarant in support of its Motion to Dismiss. Despite being served deposition notices on March 14, 2019 for a deposition on March 25, 2019, Beloteca refused to provide Mr. Defesche's testimony unless Plaintiffs agreed that his deposition would be limited to jurisdictional and venue discovery. But because Beloteca also said they would only offer Mr. Defesche for a single deposition on all issues in the case, and took a warped view of the topics they believed were outside the scope of personal jurisdiction and venue, Plaintiffs could not reasonably agree to those terms.



██████████

**2.**

Beloteca devotes only one paragraph as to whether this Court’s exercise of personal jurisdiction over it would be fair and reasonable. Motion at 21-22. In doing so, Beloteca argues the burden on it “would be great because it does not reside in, nor have any connection to, Texas,” that Illinois is an “alternate forum[] for this dispute,” and that “Texas has no interest in this dispute because neither Plaintiff resides here and [Beloteca] has not purposefully injected itself into Texas in a manner that demands this state’s attention.” Motion at 21-22. These factors alone, or even taken as true and in combination, do not even come close to showing that the exercise of personal jurisdiction over Beloteca is unreasonable.

Beloteca's argument that it faces a great burden to litigate in Texas rings hollow. Beloteca filed its declaratory judgment action against Plaintiffs in Illinois, where it neither resides nor has any connection to the State. Moreover, the Illinois Court is actually farther from San Diego, where Beloteca is located, which undermines any argument Beloteca might make about travel to this District being inconvenient. Furthermore, it appears that Beloteca has not sought any licenses to do business or sell its ISB product in Illinois. Nor does it appear that Beloteca has registered with the Illinois Secretary of State. Accordingly, all of Beloteca's arguments against this Court's exercise of personal jurisdiction would apply equally to the Illinois Court—i.e., where Beloteca in fact brought suit.

Beloteca’s claim that Illinois is an “alternate forum[] for this dispute” is incorrect. As shown *supra* VI.A.2, the Illinois Court lacks personal jurisdiction over Apicore. *See also*

Illinois MTD Brief, pp. 11-29. As such, this case could not have been properly brought in Illinois. In contrast, because Plaintiffs previously sued AuroMedics in this Court on the same patents-in-suit identified in Beloteca's declaratory judgment action, Beloteca could have brought its suit in this District (assuming subject matter jurisdiction). *See Xilinx*, 848 F.3d at 1357–58 (holding court had personal jurisdiction over defendant patent owner, in part because defendant had previously sued to enforce the patent multiple times in the district); *supra* Section VI.A.6.

Beloteca's last argument that "Texas has no interest in this dispute" is also inaccurate. Texas is one of the largest markets for ISB. As such, Texas has an interest in determining whether another product may enter the ISB market. In addition, Beloteca's ISB Product would undoubtedly compete with Plaintiffs' ISB Product in Texas, and the harm Beloteca will cause Plaintiffs in Texas is clearly foreseeable.<sup>11</sup>

Accordingly, because this Court's exercise of personal jurisdiction over Beloteca comports with due process, venue here is also proper.

**C. Because 28 U.S.C. § 1391(c) Governs Venue over Plaintiffs' Appropriately Filed Declaratory Judgment Action, Beloteca's Improper Venue Arguments Lack Merit**

As explained above, venue is proper over Beloteca in this Court pursuant to 28 U.S.C. § 1391, and none of Beloteca's arguments otherwise support a contrary finding. That is because Plaintiffs' complaint comprises a true declaratory judgment action for future patent infringement, which is distinguishable from all the cases Beloteca relies upon in trying to draw

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<sup>11</sup> Beloteca's agreement not to launch (including not sell or offer to sell) its ISB product until June 5, 2019 and violation thereof, *see* Motion for Order to Show Cause (Dkt. No. 34), is another reason why it would be fair and reasonable for this court to exercise personal jurisdiction over it. As the Court's initial order for Beloteca to submit in writing an agreement that it would not launch to preserve the status quo was made after lengthy discussions in-chambers, only this Court knows the extent of Beloteca's agreement and whether Beloteca's actions violated it.

parallels. *See Telectronics Pacing Systems v. Ventritex, Inc.*, 982 F. 2d 1520, 1526 n.6 (Fed. Cir. 1992) (“A count under the Declaratory Judgment Act should be distinguished from a count under 35 U.S.C. § 271 for patent infringement.”); *Proler Steel v. Luria Brothers*, 223 F.Supp. 87, 90-91 (S.D. Tex. 1963) (holding 1391(c) governs venue in a declaratory judgment suit brought by patentee; “Neither 1400(b) nor 1391(c) should be totally emasculated by the other. The two sections can be read so that each serves its own unique function. In this manner only suits for patent infringement fall within the terms of 1400(b), and other suits relating to patents may have their venue determined by 1391(c).”).<sup>12</sup>

First, when Plaintiffs filed their declaratory judgment complaint, Beloteca had yet to commit an act of infringement under 35 U.S.C. § 271(a). This was (but may no longer be) consistent with Beloteca’s own representations to this Court and Plaintiffs’ allegations. *See* Motion at 7, Dkt. No. 18, 19, and Tex. Complaint at ¶¶ 14, 19, 36, 50, 60 and p. 9. Thus, Plaintiffs could not have asserted a viable 35 U.S.C. § 271(a) claim for infringement. *See Lang v. Pac. Marine & Supply Co.*, 895 F.2d 761, 765 (Fed. Cir. 1990) (“[Section 271(a)] by itself, cannot be interpreted to cover acts other than an actual making, using or selling of the patented invention.”).

Second, Plaintiffs could not have asserted a 35 U.S.C. § 271(e)(2) claim against Beloteca because Beloteca was not required to, and did not file a Paragraph IV certification with its ANDA. *See* Motion at 3; *see also Eisai Co. v. Mutual Pharm. Co.*, No. 06-3613 (HAA), 2007

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<sup>12</sup> *Proler Steel* is still good law after *TC Heartland*, since it evaluated the statutes under *Fourco Glass Co. v. Transmirra Prods. Corp.*, 353 U.S. 222 (1957), whose applicability in light of the 2011 amendments to 1400(b) was acknowledged in *TC Heartland*. *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S.Ct. 1514, 1520-21 (2017).

WL 4556958, at \*12 (D.N.J. Dec. 20, 2007) (holding patentee could not “bring a claim pursuant to § 271(e)(2)” because the ANDA applicant did not submit a Paragraph IV certification).

Accordingly, because Plaintiffs had no viable claim for infringement under 28 U.S.C. 271(a) or (e)(2) when they filed their complaint, Plaintiffs are in no way circumventing the applicability of § 1400(b) “by couching [their] claim in terms of a declaratory judgment.” Motion at 14. Indeed, declaratory judgment claims were the only claims Plaintiffs had available after Beloteca made its intent to sell a competing ISB product known to Plaintiffs. *See Lang*, 895 F.2d at 764 (“If the controversy requirement is met by a sufficient allegation of immediacy and reality, we see no reason why a patentee should be unable to seek a declaration of infringement against a future infringer when a future infringer is able to maintain a declaratory judgment action for noninfringement under the same circumstances.”).

Last, the circumstances here are not at all comparable to the circumstances in other cases concerning other Mylan entities that Beloteca relies upon. *See* Motion at 13. All the district court cases Beloteca cites were Hatch-Waxman cases involving 35 U.S.C. § 271(e)(2) claims; whereas this case, as Beloteca states stridently, is not a Hatch-Waxman case. *See* Motion at 2.

At least because Beloteca relies upon the incorrect statute for venue in this action, *see* Motion at 14-16, the Court should deny its motion.

## **VII. CONCLUSION**

For the foregoing reasons, this Court should deny Beloteca’s Motion to Dismiss.

Dated: March 25, 2019

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

The undersigned certifies that all counsel of record who have consented to electronic service are being notified of the filing of this document via the Court's CM/ECF system per Local Rule CV-5(a). I also hereby certify that counsel of record are being served with a copy of the foregoing document by electronic mail on this 25<sup>th</sup> day of March, 2019.

/s/ *Melissa R. Smith*

Melissa R. Smith

